CLAIMS

1. A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form under such conditions as to provide a form which rapidly dissolves and disperses in the mouth of the consumer.

2. A process according to Claim 1, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents, which composition has a pH in the range 3.5 to 4.0, said pH being achieved by the addition of a suitable volatile acid;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form under such conditions as to volatilise the acid and provide a form which rapidly dissolves and disperses in the mouth of the consumer.

3. A process according to Claim 2, wherein the volatile acid is hydrochloric acid, acetic acid, or formic acid.

4. A process according to Claim 1, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents,

which composition has a pH in the range 3.5 to 4.0, said pH being achieved by the addition of a suitable non-volatile acid;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form to provide a form which rapidly dissolves and disperses in the mouth of the consumer when exposed to the buffering effect of saliva.

5. A process according to Claim 4, wherein the non-volatile acid is aspartame, aspartic acid, benzoic acid, citric acid, gluconic acid, glutamic acid, malic acid, phosphoric acid, saccharin, sorbic acid, succinic acid, or tartaric acid.

6. A process according to Claim 4 or 5, wherein the dosage form is buffered in the mouth to a pH of 4.0 or greater.

7. A process according to any of Claims 2 to 6, wherein the pH of the composition is adjusted in step (a) to a pH of 3.5.

8. A process according to Claim 1, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents, which composition additionally comprises one or both of the enzymes pullulanase and alginate lyase;

(b) casting said composition while still viscous into the shape of a dosage form; and

(c) drying said dosage form to provide a form which rapidly dissolves and disperses in the mouth of the consumer.

9. A process according to Claim 1, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan, sodium alginate and one or more pharmaceutically active agents;

(b) casting said composition into the shape of a dosage form;

(c) drying said dosage form; and

(d) irradiating said dosage form with gamma-radiation to provide a form which rapidly dissolves and disperses in the mouth of the consumer.

10. A process according to Claim 9, wherein said gamma-irradiation is in an amount of 25 kGy or 40 kGy.

11. A process according to any of Claims 1 to 10, wherein the solution formed upon dissolution of the resulting dosage form in the mouth of the consumer has a viscosity, which is less than 80% that of the composition formed in step (a).

12. A process according to any of Claims 1 to 11, wherein step (c) is carried out in a fan oven at a temperature of from 50°C to 80°C for a period of from 15 to 90 minutes.

13. A process according to any of Claims 1 to 11, wherein step (c) is carried out in a coating machine at a temperature of from 20°C to 150°C.

14. A dosage form obtainable according to a process described in any of Claims 1 to 13.

15. A dosage form according to Claim 14, wherein pullulan is present in an amount of from 5 to 45 wt%.

16. A dosage form according to Claim 15, wherein pullulan is present in an amount of from 15 to 25 wt%.

17. A dosage form according to Claim 16, wherein pullulan is present in an amount of 20 wt%.

18. A dosage form according to Claim 14, wherein sodium alginate is present in an amount of from 0.1 to 2.5 wt%.

19. A dosage form according to Claim 18, wherein sodium alginate is present in an amount of 0.5 wt%.

20. A dosage form according to any of Claims 14 to 19, wherein the pharmaceutically active agent is

an anti-cholesterolaemic;
an anti-diarrhoeal;
an anti-emetic;
an anti-fungal;
an anti-histamine;
an anti-infective (including anti-microbial agents);
an anti-inflammatory;
an anti-parasitic agent;
an anti-Parkinsonism drug;
an anti-pyretic (including analgesic anti-pyretics);
an anti-tussive/cough suppressant;
a bronchodilator;
an appetite stimulant;
a cardiovascular drug (including anti-hypertensives);
a decongestant;
a drug for treating gastric disorders;
a drug for renal failure;
a drug which selectively modifies CNS function;
an expectorant;
a general non-selective CNS depressant;
a general non-selective CNS stimulant;
an H_2-antagonist;

a narcotic analgesic;
a non-steroidal anti-inflammatory drug;
oral insulin;
a PDE5 inhibitor;
a proton pump inhibitor;
a psychopharmacological drug; or
a wound-healing drug.

21. A dosage form according to Claim 20, wherein the pharmaceutically active agent is ibuprofen, ivermectin, or any form of eletriptan.

22. A dosage form according to Claim 21, wherein the pharmaceutically active agent is eletriptan hydrobromide (Relpax™) or eletriptan hemisulphate.

23. A dosage form according to any of Claims 14 to 22, wherein the pharmaceutically active agent is present at a concentration of from 0.1 to 75% w/w.

24. A dosage form according to any of Claims 14 to 23, wherein the pharmaceutically active agent is an oral healthcare product.

25. A dosage form according to Claim 24, wherein the oral healthcare product is one or more of a deodorising agent, an anti-microbial agent, or a salivary stimulant.

26. A dosage form according to Claim 24 or 25, wherein the oral healthcare product is present at a concentration of from 0.1 to 15% w/w.

27. A dosage form according to any of Claims 14 to 26, which dosage form is in the form of a film.

28. A dosage form according to any of Claims 14 to 27, which dosage form is orally consumable.

29. A dosage form according to any of Claims 14 to 28, which dosage form is suitable for human or veterinary use.